NATIONAL HEALTH COUNCIL

Testimony of
Myrl Weinberg, President

Food and Drug Administration Public Meeting Regarding the Prescription Drug User Fee Act

September 15, 2000

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Re: FDA Hearing Regarding the Reauthorization of the Prescription Drug User Fee Act (PDUFA)

Good Morning. My name is Myrl Weinberg and I am President of the National Health Council. The National Health Council, a private, nonprofit umbrella organization of more than 116 national health-related organizations, works to bring quality health care to all people. Its core membership includes nearly 50 of the nation's leading voluntary health agencies, including the American Cancer Society, American Heart Association, Arthritis Foundation, National Multiple Sclerosis Society, and Lupus Foundation of America. Together, these groups represent approximately 100 million people with chronic diseases and/or disabilities. Other Council membership categories include professional and membership organizations such as the American Medical Association, nonprofit organizations with an interest in health such as AARP, and business and industry.

First, let me say that the Council considers the Prescription Drug User Fee Program to be a great success for patients, the pharmaceutical and biotechnology industry, and the Food and Drug Administration. We have seen an increase in the availability of the newest medicines for treatment of diseases such as osteoarthritis, Parkinson's Disease, cancer, and diabetes. Because of the obvious benefits of PDUFA, the Council was very active in helping to secure the reauthorization of the program in 1997. Today, the Council is once again encouraging the continuation of the program.

I want to focus my comments this morning on the specific issues raised by FDA in its announcement of this meeting.

1(a) Do you view faster drug review times as a benefit of the user fee program that should be maintained in the future?

The Council considers the user fee program an illustration of what can be achieved when government and industry work together for the benefit of all stakeholders. For some patients, having access to the latest treatments improves their quality of the life, and for others, these drugs are literally the difference between life and death. As you know, PDUFA has cut overall drug review times almost in half compared with pre-PDUFA rates. This success has been critical to patient care.

The purpose of the user fee program originally was to accelerate the review times for drugs. Setting higher goals and focussing on continuing to improve the system are key components for future PDUFA reauthorization. While drug review times are one way to gauge the success of the program, and the improved drug review times should certainly be maintained, we recommend FDA also continue to find ways to utilize technology to reduce administrative burdens on both FDA staff and drug manufacturers.

1 (b) How can the program be strengthened?

PDUFA has been successful because it provided enough resources and staff to implement a program designed with clear goals and effective evaluation measures. The drug development process can still benefit from the program by focussing on other measures of success in addition to drug review times. To maintain FDA's pattern of success, the Council recommends additional effort be made to increase access to, and use of, technology and, where possible, streamline other procedures without sacrificing high quality review.

1(c) What do you see as the downside of a regulatory agency like FDA collecting user fees and what remedies would you propose for the future?

One problem that has continued within FDA, and not because of PDUFA, is the lack of overall appropriations provided to the agency on an annual basis. In our view, this problem cannot be remedied by revising the PDUFA program, but has to come from policy-makers who decide what priority should be given to FDA and its mission.

Inadequate appropriations for FDA, combined with the requirement that FDA direct inflation-adjusted funds to the user fee program, have had a detrimental effect on other FDA functions. While user fees are intended to augment funding for the agency, they were never meant to supplant federal appropriations. The Council would like to work with all stakeholders to seek higher appropriations for FDA, and would like to see the agency given higher priority by policy-makers to avoid potentially jeopardizing public health and safety.

2. Should we continue to have performance goals for the drug and biological review process? If so, how should the goals be determined?

Performance goals are necessary to track the successes or failures of a program such as PDUFA. Due to the performance goals created in PDUFA I, the agency was able to demonstrate its great success and secure PDUFA reauthorization. Currently, FDA is meeting the goals as specified by PDUFA II. The PDUFA performance goals have been an important factor in monitoring its success and have not appeared to be unduly burdensome.

The Council supported the legislative intent of PDUFA II reforms to expedite not just the drug review process but the overall drug development process. In the future, FDA may wish to focus on more efficient methods of receiving applications, coordinating with manufacturers and keeping records. Appropriate performance measures that do not overburden administrators are necessary to track the implementation of any new goals.

3. If user fees fund FDA's drug and biological review process, what percentage of the program's costs should be covered by fees, and how should those fees be used?

While user fees are accounting for an ever-increasing percentage of overall drug review funds, the solution to any perceived conflict can be found outside the parameters of the program. The reality is that user fees are being spent to fund the activities that they were proposed to cover.

An increase in appropriations to FDA would allow the agency to increase its own spending on drug review activities and offset the rising percentage of activities funded by the private sector. Without appropriate budget increases for FDA, the alternative will be to limit resources for drug review and jeopardize the success of the program, and, in turn, decrease patient access to advanced treatments.

4. Should fees collected from the industry be used to pay for other costs FDA incurs to assure that drugs in the American marketplace are safe and effective?

As other functions of FDA experience budget restrictions, one obvious potential reaction is to tap into the resources provided by the user fee program. While on its face this approach may appear logical, there are several reasons that the Council cautions FDA from pursuing this strategy.

First, it was made quite clear in the original drafting of the PDUFA statute that user fees would not supplant federal appropriations. The user fees are providing a valuable resource to the agency to fund restricted activities of the agency. The user fees are tied to the performance of the agency so that the success of the program can be determined.

Second, the activities FDA is considering be funded by user fees are not activities that are appropriate for user fees. Congress never intended that these fees be used for activities other than enhancing the drug review or the drug development process. While the public benefits from withdrawal of unsafe products, it is not the purpose of user fees to fund inspections or post-marketing monitoring activities.

Finally, he Council agrees that the need for monitoring adverse events is as great as ever, and important to protecting public health. The good news is that there is no evidence that the withdrawal rate of drugs from the market has increased since the enactment of PDUFA in 1992. The Council recommends that any additional funding for activities related to post-marketing monitoring should come from increased appropriations. Redirecting a portion of user fees outside the program could reduce the program's effectiveness and result in funding for activities for which there are no specific metrics to gauge success.

I would like to thank FDA for allowing the National Health Council to share our comments regarding the PDUFA program. I also pledge to continue and enhance the efforts of the Council and its member organizations to secure higher appropriations for FDA. On behalf of those patients who have benefited from new treatments, and for those who are still waiting for a breakthrough therapy, the Council urges FDA to continue to direct user fees as directed under PDUFA II.